

REMARKS

I. Status of Claims

Claims 1-10 are pending in the subject U.S. patent application. Claims 1-6 have been rejected by the U.S. Patent and Trademark Office (hereinafter "the Patent Office"). Claims 7-10 currently stand withdrawn.

Claims 1-6 have been amended. Withdrawn claim 9 has also been amended. Support for the amendments can be found in the specification as originally filed. No new matter has been added.

Reconsideration of the application as amended and further in view of the remarks set forth herein below is respectfully requested.

II. Response to Rejections under 35 U.S.C. § 112, second paragraph

Claims 1-6 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. In particular, the Patent Office contends that the phrase "that is absent or almost absent" in claim 1 is unclear because it is uncertain if the antigen, the HEC-GlcNAc6ST gene, reactivity of the antibody, or GlcNAc-6-sulfotransferase is absent and it is further uncertain what is meant by "almost" absent. The Patent Office contends that the terms "react," "reacting," and "reactivity" in claims 1, 5, and 6 are unclear. The Patent Office alleges that antibodies "bind" to antigens, but do not "react" with antigens unless they are catalytic. Further, the Patent Office alleges that it is unclear what is meant by "equivalent" in claim 5 in the phrase "MECA-79 antibody or its equivalent."

After careful consideration of the rejection and the Patent Office's bases therefore, applicants respectfully traverse the rejection and offer the following remarks.

Initially, while applicants respectfully submit that one of skill in the art would have understood that "react," "reacting," and "reactivity" are referring to binding, and without acquiescing to the Patent Office's remarks, claims 1, 5, and 6 have been amended herein in order to expedite prosecution of the claims. More particularly, claim 1 has been amended herein to recite that the method comprises assaying the "binding" of an

antibody. Claim 5 has also been amended to recite "binding" rather than "reactivity." Claim 6 has been amended to recite "binding a labeled probe." Support for the amendments can be found in claims 1, 5, and 6 as originally filed.

Applicants respectfully submit that claims 1 and 2 have been amended to delete the phrase "or almost absent."

Further, applicants respectfully submit that claim 1 has been amended to recite the binding of an antibody to an antigen "wherein said antigen is present in cells expressing HEC-GlcNAc6ST gene encoding GlcNAc-6-sulfotransferase and is absent in cells expressing GlcNAc6ST-1 or I-GlcNAc6ST." Support for the amendment can be found in claim 1 as filed. Additional support with regard to the antigen being absent in cells expressing GlcNAc6ST-1 or I-GlcNAc6ST gene can be found in the specification at page 3, lines 23-26, which recites that it was found that colorectal cancers and adenomas could be detected specifically by assaying 6-sulfated sugar residues which are synthesized by HEC-GlcNAc6ST, but not by GlcNAc6ST-1 nor by I-GlcNAc6ST. See also Instant Specification, page 4, lines 12-15. Accordingly, applicants respectfully submit that one of skill in the art would understand that the method of claim 1 is directed to assaying the binding of antibodies to antigens (i.e., certain compounds comprising 6-sulfated sugars), wherein the antigens are present in some cells, but not in others.

Claim 5 has been amended to recite "comprising assaying the binding of MECA-79 antibody or another antibody having the same binding specificity with tissues" Support for the amendments can be found in claim 5 as filed and in the instant specification at page 4, lines 2-5, which recites that a search was made for antibodies having strong reactivity to sulfated sugar residues in cancer cells, but not sulfated sugar residues in normal cells.

Accordingly, applicants respectfully submit that claims 1-6 are believed to be in compliance with 35 U.S.C. § 112, second paragraph. Applicants respectfully request the withdrawal of the rejection of claims 1-6 under 35 U.S.C. § 112, second paragraph and further ask that claims 1-6 be allowed at this time.

III. Response to Rejections under 35 U.S.C. § 102 over Streeter as evidenced by Hemmerich

Claims 1-6 have been rejected under 35 U.S.C. § 102(b) as allegedly being unpatentable over Streeter et al. (*J. Cell Biology*, 107, 1853-1862 (1988); hereinafter "Streeter") as evidenced by Hemmerich et al. (*Immunity*, 15, 237-247 (2001); hereinafter "Hemmerich"). The Patent Office contends that Streeter teaches a method of staining tissue from the small intestine and colon with MECA-79 antibody. The Patent Office contends that the binding of MECA-79 antibody to its antigen present in cells expressing a HEC-GlcNAc6ST gene encoding GlcNAc-6-sulfotransferase would be an inherent feature of the antibody. The Patent Office contends that Hemmerich supports this inherency by disclosing staining of tissue samples expressing HEC-GlcNAc6ST by the MECA-79 antibody.

After careful consideration of the rejection and the Patent Office's comments, applicants respectfully traverse the rejection and offer the following remarks.

Initially, applicants respectfully submit that claim 1 is directed to a method of examining colorectal cancer and colorectal adenoma by assaying for the binding of an antibody to a antigen (i.e., GlcNAc-6-sulfated sugar residues) present in cancer or adenoma cells (i.e., cells expressing HEC-GlcNAc6ST gene) but not present in normal cells (i.e., cells expressing GlcNAc6ST-1 or I-GlcNAc6ST gene). The presently disclosed subject matter is based, at least in part, on the finding that there are differences in the distribution of GlcNAc-6-sulfotransferase isozymes between colorectal cancer or adenoma tissues and normal colorectal tissue and the finding that colorectal cancer or adenoma cells can be detected by assaying for certain types of 6-sulfated sugar residues. See Instant Specification, page 3, lines 20-26. See also, Instant Specification, abstract.

Applicants respectfully submit that neither Streeter or Hemmerich describe a method of examining colorectal cancer or colorectal adenoma by detecting an antigen that is present in cells expressing a HEC-GlcNAc6ST gene and absent in cells

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expressing GlcNAc6St-1 or I-GlcNAc6ST genes. Nor do Streeter and Hemmerich describe any method of examining colorectal cancer or colorectal adenoma.

Accordingly, applicants respectfully request the withdrawal of the rejection of claims 1-6 under 35 U.S.C. § 102(b) over Streeter as evidenced by Hemmerich and further ask that claims 1-6 be allowed at this time.

IV. Other Amendments

Applicants respectfully submit that claims 3, 4, and 6, and withdrawn claim 9 have been amended herein to reflect amendments presented in the first Preliminary Amendment filed on February 17, 2006. These amendments were inadvertently omitted from the claims as presented in the second Preliminary Amendment filed with the Response to Restriction/Election Requirement filed on March 18, 2008. Thus, for the sake of clarity, the amendments have been re-presented herein. More particularly, claims 3, 4, and 6 have been amended from multiple dependent form to single dependent form. Further, in claims 3 and 9, the punctuation mark following the phrase "limited in structure" has been changed from a period to a semi-colon. No new matter has been added.

CONCLUSIONS

Should there be any minor issues outstanding in this matter the Examiner is respectfully requested to telephone the undersigned attorney. Early passage of the subject application to issue is earnestly solicited.

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DEPOSIT ACCOUNT

The Commissioner is hereby authorized to charge any fees associated with the filing of this correspondence to Deposit Account Number 50-0426.

Respectfully submitted,

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Date: October 21, 2008

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